

**CREDENTIALING OF PERSONNEL
INVOLVED IN RESEARCH**

- 1. PURPOSE:** To establish a research service level policy that identifies personnel involved in human, animal and laboratory research and/or who have a healthcare license or certification, or a degree offering the potential for a healthcare license or certification (MD, RN, BSN, Medical Technician, Audiologist, etc.), and a compliance system for credentialing such personnel. Credentialing is defined as the formal, systematic process of verifying, screening, and evaluating qualifications and other credentials (VHA Directive 2003-036). This policy requires that the education/training, certification(s) and healthcare license(s) of all personnel involved in human research be verified, that a Scope of Work for each individual on each IRB-approved protocol be completed by the principal investigator (PI) and signed by the PI, employee, and ACOS/R&D, and that files be maintained for all credentialed and approved employees. Such credentialing will add assurance that personnel are appropriately educated, certified, and/or healthcare licensed to effectively and safely perform human research at the Portland VA Medical Center (PVAMC). The policy will also assist in assuring only those with appropriate credentials will be involved with human research.
- 2. POLICY:** All research personnel must be credentialed. Human Resources is responsible for verifying the education and training of all research employees. The Research and Development (R&D) Service is responsible for determining which individuals require credentialing in the web-based Federal Credentialing Program for Healthcare Providers (VetPro). Those requiring VetPro credentialing include all who have a healthcare license or certification (e.g., medical license, nursing license, American Speech-Language-Hearing Association (ASHA) certification EMT, MRI Technician), OR training that offers the potential for such licensure or certification OR a degree offering the potential for either (e.g., MD, BSN, MSW, Medical Technician, LPN, BS Pharmacy,). All research personnel must submit an Education Verification form and a Scope of Work signed by their supervisor and any principal investigators of research in which they may be involved to the R&D Service.

*EXCEPTION to requirement for VetPro: Residents/fellows/clinical trainees must be verified via a Resident Credentials Verification Letter (RCVL) from the Medical Professional Service Office, or in the case of trainees in Mental Health, a Trainee Qualifications and Credentials Verification Letter (TQCVL) from the Education Office. Any resident/fellow/trainee from OHSU who will not have a clinical rotation and will only work in VA research at PVAMC and therefore does not have an RCVL or TQCVL on file at PVAMC must be credentialed in VetPro.

a. Individuals involved in human research at the PVAMC must have their credentials verified, prior to working on PVAMC Institutional Review Board (IRB) approved research projects. Such credentialing includes VetPro and RCVL/TQCVL when applicable and a Scope of Work form specific to each human research protocol.

3. RESPONSIBILITIES:

- a. The **Associate or Deputy Associate Chief of Staff for Research & Development (ACOS/R&D)** is responsible for:
 - (1) Completing credentialing requirements, as defined by national and local policy.
 - (2) Developing and managing credentialing policies and procedures for personnel involved in human research and for all personnel with degrees that offer the potential for licensure or certification in an area of patient care at the PVAMC, whether or not such a healthcare license or certification is held or required for their research duties at PVAMC.
 - (3) Ensuring that all PVAMC research personnel have completed the appropriate credentialing requirements consistent with VA policy.
- b. The **Administrative Officer for Research & Development (AO/R&D)** is responsible for:
 - (1) Completing credentialing requirements as defined by national and local policy with the exception of the Scope of Work Form.
 - (2) Overseeing the Research Service staff involved with the credentialing of personnel involved in research.
 - (3) Working with Human Resources to ensure without compensation (WOC) appointments are complete when appropriate (see 4.b.(2) below).
 - (4) Reviewing all Scope of Work forms for those working in animal or laboratory research, signing for the ACOS/R&D, consulting with the ACOS/R&D if any questions about qualifications for any procedures.
 - (5) Maintaining Scope of Work files for all non-human research personnel.
- c. The **Research and Development Committee (R&D) Members** are responsible for completing credentialing requirements, with the exception of the Scope of Work Form.
- d. The **Research and Development Committee (R&D) Coordinator** is responsible for completing credentialing requirements.
- e. The **Institutional Review Board Members** are responsible for completing credentialing requirements.
- f. The **Institutional Review Board Coordinators** are responsible for:
 - (1) completing credentialing requirements.
 - (2) Prior to IRB review, forwarding all Scope of Work forms to the Research Assurance Officer (RAO) and checking the Research Personnel Database before final IRB approval assure that all personnel on the project have successfully completed the credentialing requirements.
- g. **Human Resources Management Service** is responsible for:
 - (1) assuring that all research employees meet all requirements for appointment, and informing the AO for R&D of any non-compliance with appointment requirements.

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- h. A **Research Service Staff Member** (designated by AO) is responsible for:
- (1) Identifying and credentialing PVAMC research personnel who have healthcare licensure/registration/certification or the potential for such, and credentialing as appropriate.
 - (2) Requesting VetPro credentialing through Medical Professional Service or Nursing Professional Service as appropriate and documenting the VetPro appointment and expiration date in the Research Personnel Database.
 - (3) Assuring an RCVL or TQCVL is on file and recording the expiration date in the Research Personnel Database.
 - (4) Monitoring personnel compliance with the credentialing requirements.
 - (5) Reviewing all Scope of Work forms, signing for the ACOS/R&D, consulting with the ACOS/R&D if any questions about qualifications for any procedures.
 - (6) Informing the AO/R&D and ACOS/R&D of areas of non-compliance with credentialing requirements.
 - (7) Maintaining the human research section of the Personnel Database.
 - (8) On a monthly basis, assuring all research appointees in human research are not the subject of regulatory action, and have completed all credentialing requirements.
 - (9) Maintaining documentation of Scope of Work and Education Verification for all personnel working in human research and for research personnel with licensure or certification or potential for either.
- i. The **Research Assurance Officer (RAO)** is responsible for reporting quality assurance review of research personnel annually to the R&D Committee.
- j. **Personnel involved with PVAMC IRB-approved research projects** are responsible for completing credentialing requirements prior to participating in PVAMC IRB-approved research projects.

4. PROCEDURES:

- a. **Research Personnel** include PVAMC paid employees (Title 5 and 38), Portland VA Research Foundation Employees (PVARF), Oregon Health & Science University (OHSU) employees or others with without compensation (WOC) appointments. Information is available on the R&D website at <http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp>. Research staff must have a VA-paid or WOC appointment if they
- (1) work on PVAMC property,
 - (2) interact with VA research participants via telephone or in person except as listed in item b.(1) below;
 - (3) collect and analyze identifiable patient laboratory specimens or patient data of participants in a VA IRB-approved study;
 - (4) perform patient laboratory tests or work with identifiable patient data of participants in VA research studies;
 - (5) work in the R&D Office, i.e. ACOS/R&D, Deputy ACOS/R&D, AO/R&D, R&D Committee Coordinator, IRB Coordinators, R&D Staff, and RAO; or
 - (6) serve as R&D Committee and/or IRB members.

- b. **Personnel involved in PVAMC IRB-approved human research projects who meet the following criteria are NOT required to complete the credentialing requirements:**
- (1) Members of the research team who are strictly administrative staff, e.g., receptionist or any individuals that may have contact with a patient for scheduling purposes only.
 - (2) Members of the research team, e.g., biostatisticians or lab technicians who do not come to the PVAMC and do not directly interact with VA research participants or see their identifiable specimens or data (do not require a WOC appointment or credentialing).
 - (3) Volunteers from the community who serve on an IRB or R&D Committee and members of groups such as Data Safety Monitoring Boards (DSMBs) who are recruited from non-VA institutions.
- c. **Individuals who do not meet the criteria above in item b. and are applying for either VA-paid or WOC research appointments (unpaid volunteer or paid by PVARF, OHSU, or some other outside entity) must submit the following to the R&D Office** (see R&D website [Hiring and New Employee Information](http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp#checklists)):
- (1) The applicable checklist (see <http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp#checklists>);
 - (2) All applicable forms available at <http://www.portland.va.gov/research/piservices/hiring/appointmentrequirements.asp#forms> including
 - Scope of Work forms for human and for animal or basic science research and
 - an Education Verification Form;
- d. **R&D Office staff designated by the AO/R&D will be responsible for the following:**
- (1) Review of Scope of Work, follow-up concerning any questionable procedures, and obtain signature of ACOS/R&D.
 - (2) For those with healthcare license or certification or the potential for either, assuring VetPro credentialing, and if necessary, submitting a request for VetPro credentialing to Medical Professional Services or Nursing Professional Services, as applicable.
 - (3) For medical residents/fellows/trainees, assuring a current RCVL/TQCVL is on file.
 - (4) Maintaining credentialing files for all working in human research and/or who require VetPro credentialing.
 - (5) In the event an individual appears on any exclusionary list or is found to have an expired license, the AO/R&D and ACOS and Deputy ACOS/R&D will be notified immediately. Appropriate action will be taken with consultation from Human Resources Division. The following will be checked monthly:
 - The FDA Debarment List and FDA Disqualified/Restricted/Assurance List for Clinical Investigators on the FDA website.
 - The Public Health Service Administrative Actions Listing.

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- The R&D Personnel Database for expired VetPro appointments and residency/fellowships.

e. **Background Investigations:** Individuals involved in human research must have background investigations related to the risk level of their position. This is part of the normal VA hiring process. The Research Service will adhere to the Human Resources Division policies for background investigations, consistent with VA policy.
(1) VA employees must have a full background investigation.
(2) All individuals with a WOC appointment must be fingerprinted. If the results of the fingerprinting are questionable, a full background investigation must be completed.

f. **Record Retention:** Human research credentialing files will be maintained for a minimum of six years after the termination date of the appointment and then indefinitely until instructions are received from the Government Archives.

5. REFERENCES: VHA Directive 2006-067, Credentialing of Health Care Professionals; 1/26/2007 ORO Memo, Credentialing And Privileging Of Research Staff; ; VHA Directive 2009-054; VHA Directive 1200.

6. CONCURRENCES: Endorsed by the Research & Development Committee on 2/7/2011.

7. RESCISSION: HRPP: P&P No. 10, Endorsed by the Research & Development Committee on 01/26/2004, 04/04/2005, 08/01/2005, 4/6/2009 and 08/30/2010.

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

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